

DEA Issues Interim Final Rule for Electronic Prescriptions of Schedules II, III, IV, and V Controlled Substances

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On March 24, 2010, the Drug Enforcement Administration (DEA) of the U.S. Department of Justice released a new interim final rule which, for the first time, will permit the electronic prescribing of schedule II, III, IV, and V controlled substances. The interim final rule appeared in the March 31, 2010, *Federal Register* and is currently targeted to become effective on June 1, 2010 (Interim Final Rule).¹ The Interim Final Rule has been identified as a "major rule" under the Congressional Review Act (*i.e.*, a rule that has resulted in or is likely to result in: (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets).² Significantly, the DEA will be accepting public comments **through June 1, 2010**. Key issues are described below. Stakeholders should consider filing comments notwithstanding the fact that this is an Interim Final Rule. Such public comments can continue to affect the content in the future.

Subject to the requirements of the Interim Final Rule and any other relevant requirements (*e.g.*, State Board of Pharmacy and third-party payor requirements), practitioners will be permitted to electronically write, and pharmacies will be permitted to electronically receive, dispense, and archive, prescriptions for schedule II, III, IV, and V controlled substances. In the preamble to the Interim Final Rule, the DEA acknowledged a number of government electronic prescribing incentives and identified that electronic prescribing has the potential to reduce: (1) paperwork, (2) prescription forgery, and (3) prescription errors. However, the DEA made clear that it is not

¹ [Access](#) the Interim Final Rule and related guidance.

² Under the Congressional Review Act, major rules are subject to U.S. Government Accountability Office and Congressional review, and the effective date may change as a result of such reviews. In addition, the Congressional Review Act outlines a Congressional disapproval procedure. See 5 U.S.C. § 801.

requiring electronic prescribing (*i.e.*, practitioners will be able to continue to comply with the existing hard-copy prescription requirements).

For many stakeholders, the DEA's existing prescription requirements for certain controlled substances (*i.e.*, writing and signature requirements) have been a substantial obstacle to the adoption of electronic prescribing for these particular controlled substances. Therefore, this Interim Final Rule has the potential to substantially change the ways in which prescriptions for schedule II, III IV and V controlled substances are handled by a large number of stakeholders in the health care community.

The Interim Final Rule addresses a number of requirements that various stakeholders in the electronic prescribing community (including practitioners, institutional providers, pharmacies and vendors) must comply with, including:

- Electronic prescribing application (*i.e.*, system) requirements, including access controls, incident reporting, third-party audit/certification requirements, etc. (Note: There are different requirements for practitioner and pharmacy systems);
- Electronic prescribing application provider (*i.e.*, vendor) requirements, including third-party audit requirements;
- Security requirements (*e.g.*, security of practitioner security tokens);
- Notification requirements (*e.g.*, loss, theft, or compromise of a security token, failed transmission of an electronic prescription, security incidents, unapproved prescriptions, etc.);
- Individual practitioner authentication credentialing requirements, including requirements related to when individual practitioners use an electronic prescription application (*i.e.*, a system) of an institutional practitioner (*e.g.*, a hospital);
- Requirements for creating an electronic controlled substances prescription;
- Electronic prescribing signature requirements;
- Electronic prescription transmission requirements;
- Electronic prescription copying/duplication requirements; and
- Archiving and record-keeping requirements.

The DEA provided that it balanced several considerations in issuing the Interim Final Rule:

Chief among these is DEA's obligation to ensure that the regulations minimize, to the greatest extent possible, the potential for diversion of controlled substances resulting from nonregistrants gaining access to electronic prescription applications and electronic prescriptions. At the same time, DEA has sought to streamline the rules to reduce the burden on registrants. Another of DEA's goals has been to provide flexibility in the rule so that as technologies and standards mature,

registrants and application providers will be able to take advantage of advances without having to wait for a revision to the regulations.³

The DEA will be accepting public comments on or before June 1, 2010. Significantly, the DEA is soliciting specific comments for the following key issues:

- Identity proofing (*i.e.*, verifying that an individual is who an individual claims to be);
- Access control (*i.e.*, verifying that the authenticated individual has the authority to perform the requested operation);
- Authentication (*i.e.*, security measures used to verify an individual's authorization);
- Biometric subsystems (*i.e.*, products that recognize an individual based on a physiological or behavioral characteristic) and testing of those subsystems;
- Internal audit trails for electronic prescribing applications (*e.g.*, recording modifications, annotations, or deletions of an electronic controlled substance prescription and recording when a required element of the electronic prescribing system is modified); and
- Third-party auditors and certification organizations (*e.g.*, those entities that will review electronic prescription systems).

Stakeholders should review this Interim Final Rule and consider filing comments. Such comments can be on the specific key issues cited by the DEA as well on any other issue of importance. Public comments are due June 1, 2010.

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*This Client Alert was authored by **Jason Caron, Ben Martin, Lee Rosebush and Dan Gottlieb**. For additional information about the issues discussed in this Client Alert, please contact one of the authors or contributors or the EpsteinBeckerGreen attorney who regularly handles your legal matters.*

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³ Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16,236, 16,241-42 (March 31, 2010).

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